

(70171)

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Preauthorization	Yes	Review Dates: 02/07, 01/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Lung volume reduction surgery (LVRS) is proposed as a treatment option for patients with severe emphysema who have failed optimal medical management. The procedure involves the excision of diseased lung tissue and aims to reduce symptoms and improve quality of life.

Background

Lung volume reduction is a surgical treatment for patients with severe emphysema involving the excision of peripheral emphysematous lung tissue, generally from both upper lobes. The precise mechanism of clinical improvement for patients undergoing lung reduction surgery has not been firmly established. However, it is believed that elastic recoil and diaphragmatic function are improved by reducing the volume of diseased lung. In addition to changes in chest wall and respiratory mechanics, the surgery is purported to correct ventilation perfusion mismatch and improve right ventricular filling.

Research on LVRS has focused on defining the sub-group of patients most likely to benefit from the procedure. Potential benefits of the procedure, e.g., improvement in functional capacity and quality of life must be weighed against the potential risk of the procedure, e.g., risk of post-operative mortality.

Related Protocol:

Outpatient Pulmonary Rehabilitation

Corporate Medical Guideline

Lung volume reduction surgery as a treatment for emphysema may be considered **medically necessary** in patients with emphysema who meet ALL of the following criteria*:

- Predominantly upper lobe emphysema with hyperinflation and heterogeneity (i.e., target areas for removal)
- Forced expiratory volume in one second (FEV-1):
 - For patients who are younger than 70 years of age, the FEV-1 must be no more than 45% of the predicted value
 - For patients who are 70 years of age or older, the FEV-1 must be no more than 45% of the predicted value and greater than or equal to 15% of the predicted value
- Marked restriction in activities of daily living despite maximal medical therapy
- Age younger than 75 years

- Acceptable nutrition status; i.e., 70%–130% of ideal body weight
- Ability to participate in a vigorous pulmonary rehabilitation program
- No coexisting major medical problems that would significantly increase operative risk
- Willingness to undertake risk of morbidity and mortality associated with LVRS
- Abstinence from cigarette smoking for at least four months.

Lung volume reduction surgery is considered **investigational** in all other patients.

*Patient selection criteria are based on the National Emphysema Treatment Trial.

Policy Guideline

The following additional criteria, also from the NETT trial, may provide further information in determining whether a patient is a candidate for lung volume reduction surgery:

- PaO₂ on room air greater than or equal to 45 mm Hg (greater than or equal to 30 mm Hg at elevations of 5,000 feet or higher)
- PaCO₂ on room air less than or equal to 60 mm Hg (less than or equal to 55 mm Hg at elevations of 5,000 feet or higher)
- Post-rehabilitation six-minute walk of at least 140 m, and able to complete three min. unloaded pedaling in exercise tolerance test.

Medicare Advantage

For Medicare Advantage, Lung Volume Reduction Surgery (LVRS) is **medically necessary** when:

1. The patient satisfies all the criteria outlined below:

Assessment	Criteria
History and physical examination	Consistent with emphysema
	BMI, $\leq 31.1 \text{ kg/m}^2$ (men) or $\leq 32.3 \text{ kg/m}^2$ (women)
	Stable with $\leq 20 \text{ mg}$ prednisone (or equivalent) qd
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second (FEV ₁) $\leq 45\%$ predicted $\geq 15\%$ predicted if age ≥ 70 years
	Total lung capacity (TLC) $\geq 100\%$ predicted post-bronchodilator
	Residual volume (RV) $\geq 150\%$ predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	PCO ₂ , $\leq 60 \text{ mm Hg}$ (PCO ₂ , $\leq 55 \text{ mm Hg}$ if 1-mile above sea level)
	PO ₂ , $\geq 45 \text{ mm Hg}$ on room air (PO ₂ , $\geq 30 \text{ mm Hg}$ if 1-mile above sea level)
Cardiac assessment	Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF < 45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (> 5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest)
Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation
Exercise	Post-rehabilitation six-min. walk of $\geq 140 \text{ m}$; able to complete three min. unloaded

Assessment	Criteria
	pedaling in exercise tolerance test (pre- and post-rehabilitation)
Consent	Signed consents for screening and rehabilitation
Smoking	Plasma cotinine level \leq 13.7 ng/mL (or arterial carboxyhemoglobin \leq 2.5% if using nicotine products)
	Nonsmoking for four months prior to initial interview and throughout evaluation for surgery
Preoperative diagnostic and therapeutic program adherence	Must complete assessment for and program of preoperative services in preparation for surgery

In addition, the patient must have:

- Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan), or
- Severe non-upper lobe emphysema with low exercise capacity.

Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts (w) for men after completion of the preoperative therapeutic program in preparation for LVRS. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing five or 10 watt/minute ramp on 30% oxygen after three minutes of unloaded pedaling.

2. Also, LVRS is **medically necessary** only when performed at facilities that are:

- Certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet);
- Approved as Medicare lung or heart-lung transplantation hospitals;
- Were approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial (NETT); or
- Are approved as Medicare lung or heart-lung transplantation hospitals.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at <https://www.cms.hhs.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage>.

The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to maximize the patient's potential to successfully undergo and recover from surgery. The program must include a six- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of two hours. It must also include at least six, and no more than 10, postoperative sessions, each lasting a minimum of two hours, within eight to nine weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

LVRS is **not medically necessary** in any of the following clinical circumstances:

1. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;
2. The disease is unsuitable for LVRS;
3. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery;

4. The patient presents with FEV-1 < 20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of < 20% of predicted value (high-risk group identified October 2001 by the NETT); or
5. The patient satisfies the criteria outlined above in section B(1), and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

All other indications for LVRS are **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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4. Tiong LU, Davies R, Gibson PG et al. Lung volume reduction surgery for diffuse emphysema. *Cochrane Database Syst Rev* 2006; (4):CD001001.
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7. Miller JD, Malthaner RA, Goldsmith CH et al. A randomized clinical trial of lung volume reduction surgery versus best medical care for patients with advanced emphysema: a two-year study from Canada. *Ann Thorac Surg* 2006; 81(1):314-20; discussion 20-1.
8. Baldi S, Oliaro A, Tabbia G et al. Lung volume reduction surgery 10 years later. *J Cardiovasc Surg (Torino)* 2012; 53(6):809-15.

9. American Thoracic Society. Lung volume reduction surgery. 1996. Available online at: www.thoracic.org/statements. Last accessed May, 2013.
10. Center for Medicare and Medicaid Services. National coverage determination for lung volume reduction surgery (reduction pneumoplasty) (240.1). 2005. Available online at: www.cms.hhs.gov. Last accessed May, 2013.